UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND

NORTHERN DIVISION

Matthew Ashley, individually and on behalf of all others similarly situated,	Plaintiff's Address and County:
	143 Brynwood St Hagerstown MD 21740 Washington County
Plaintiff,	1:23-cv-01486
- against -	Class Action Complaint
	Defendant's Address:
Chain Drug Marketing Association, Inc.,	43157 W 9 Mile Rd Novi MI 48375
Defendant	Jury Trial Demanded

Plaintiff alleges upon information and belief, except for allegations about Plaintiff, which are based on personal knowledge:

1. Chain Drug Marketing Association, Inc. ("Defendant" or "CDMA") sells adhesive patches promising to deliver 4% lidocaine under the Quality Choice brand ("Product").

2. The representations include its description as a "Maximum Strength" "Lidocaine Pain Relief Patch" delivering "4% Lidocaine [as a] Topical Anesthetic," and invites purchasers to "Compare [it] to Aspercreme Lidocaine Patch active ingredient*."

3. The label indicates it "Desensitizes Aggravated Nerves and Relieves Pain" through a "Stay-put Flexible Patch" in a "Single Use Application" that "Lasts up to 12 Hours."

4. These statements are presented next to a human figure with a patch applied to the lower back, with red, concentric circles of varying thickness, radiating from the center, indicating the Product's ability to relieve pain beyond the location it is placed on the body.

I. LIDOCAINE BACKGROUND

5. Lidocaine is a topical anesthetic used to treat pain by blocking the transmission of pain signals from nerve endings in the skin to the spinal cord and brain.

6. In 1983, the Food and Drug Administration ("FDA") issued requirements for the labeling, ingredients, uses, and doses of external analgesic products, allowing the use of lidocaine at 4% in an ointment form.[1]

7. The first lidocaine patch required a prescription and was approved in 1999 to help reduce pain associated with post-herpetic neuralgia ("PHN"), a complication of shingles.

8. In 2003, the FDA began reviewing over-the-counter ("OTC") lidocaine patches to determine the safe and effective concentration of this ingredient in this format.

9. Doctors discovered that certain lidocaine patches can be effective in treating general neuropathic pain like muscle and spinal aches and began prescribing the patches off-label.

10. As the use of lidocaine patches increased, national brands such as Salonpas and Aspercreme spent significant amounts of money to develop and advertise their over-the-counter

[1] This State has adopted the identical relevant federal regulations.

("OTC") patches as equivalent to those available only with a prescription.

11. A 2012 study found that over 82% of the usage of prescription lidocaine patches were off-label.

12. In 2013, the FDA concluded that lidocaine patches were not "generally recognized as safe and effective" for OTC use because there was insufficient information about, among other things, their effectiveness and adherence.

II. PRODUCT FAILS TO DELIVER LIDOCAINE IN PROMISED WAY DUE TO ADHESION DEFECTS

A. How Lidocaine Patches Work

13. Lidocaine patches use transdermal/topical delivery systems ("TDS") which have three main parts: (1) an outer protective backing membrane, (2) a drug-in-adhesive ("DIA") layer, and (3) a release liner that controls the rate and extent of drug administration.

14. Since the FDA did not contemplate the delivery of lidocaine in patch form, their strength cannot be evaluated based on its previously issued guidance.

15. Manufacturers of lidocaine patches like Defendant attempt to meet the FDA's 4% benchmark based on the mass of drug relative to the mass of the adhesive per patch.

16. However, the amount of lidocaine contained in, or delivered by, a lidocaine patch cannot be determined based on the arbitrary measure of a patch's drug-to-adhesive ratio.

17. This allows Defendant to alter the total mass of lidocaine in the Product by adjusting the thickness of its back membrane without changing its dimensions.

18. The result is that purchasers and doctors are misled by the Product's drug-to-adhesive ratio, because they expect the percentage of an active ingredient has a direct correlation to the quantity, or efficacy, of that ingredient within the delivery mechanism.

B. Adhesion Failure Defects

19. Since adequate adhesion is critical to delivery in the form of a patch, any lifting or detaching while walking, sleeping or exercising will compromise dosing.

20. The FDA Adverse Events Reporting System ("AERS") revealed that approximately 70% of consumer complaints about lidocaine patches, including upon information and belief, Defendant's Product, relate to their poor adhesion.

21. The FDA concluded that because the patches systemically fail to adhere to the body, they cannot provide the claimed pain relief.

22. A January 2021 peer-reviewed study in the Journal of Pain Research analyzed store brand or private label lidocaine patches, substantially similar and/or identical to the Quality Choice lidocaine patch, and concluded that none of them exceeded ninety percent adhesion within the twelve-hour testing period.

23. Rather, their average adhesion after twelve hours was less than forty percent.

24. This was based on a scale where zero reflected complete detachment and fifty percent meant half the patch lifted off the skin but did not fully detach.

25. These findings understated the poor adhesion qualities of private label lidocaine patches, because study participants were required to remain sedentary during the time the patches were applied, whereas typical users will be walking, exercising, sleeping and otherwise attempting to function normally.

26. Although the study tested generic lidocaine patches, a comparison between the samples analyzed and Defendant's Product reveals they both use the same defective adhesion technology, which has not undergone the rigorous FDA approval process.

27. Though other companies have innovated their technology based on clinical studies and research to ensure their lidocaine patches are sufficiently flexible to adhere to a user's body

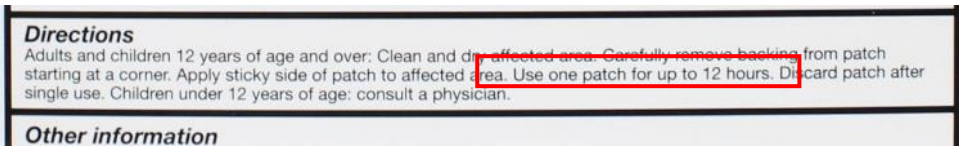
during everyday activity, upon information and belief, Defendant has not.

28. This is crucial because "[a]dequate adhesion is a critical quality attribute for topical delivery systems; if the product lifts or detaches during wear, dosing may be compromised and there is an increased risk of inadvertent exposure to others."

29. Since the Product cannot adhere to a person's skin throughout the promised time period, it cannot deliver the active anesthetic ingredient of lidocaine during that time.

30. When prospective purchasers see that the Product claims to "Desensitize[s] Aggravated Nerves and Relieves Pain" through a "Stay-put Flexible Patch" in a "Single Use Application" that "Lasts up to 12 Hours," they will expect it to adhere to their bodies for close to or no less than twelve hours.

31. This is confirmed by the Directions on the back-panel Drug Facts, which tells users to "Use one patch for up to 12 hours" and "Discard [the] patch after [a] single use."


Directions
Adults and children 12 years of age and over: Clean and dry affected area. Carefully remove backing from patch starting at a corner. Apply sticky side of patch to affected area. Use one patch for up to 12 hours. Discard patch after single use. Children under 12 years of age: consult a physician.

Other information

32. However, the Product cannot and does not adhere for anywhere close to twelve hours, which renders the Directions misleading, because it assumes it will not have detached by then.

33. The above-referenced studies, among others, have shown that lidocaine patches using the same or substantially similar delivery mechanism and design are unable to adhere to the body for more than four hours, often peeling off within minutes of light activity, nowhere near the twelve hours of usage time indicated.

34. This inability to adequately adhere during normal use renders the adhesion claims, "Stay-put Flexible Patch," "Single Use Application" and "Lasts up to 12 Hours" misleading due to the significant disparity between what is promised and what is delivered.

III. MAXIMUM STRENGTH CLAIM IS MISLEADING

35. The representation of "Maximum Strength" and "4% lidocaine" is misleading for multiple reasons.

36. First, prescription lidocaine patches exist on the market that deliver greater amounts of lidocaine to the wearer.

37. This includes patches with 5% and 1.8% lidocaine, with the latter utilizing advanced technology to maximize bioavailability, so greater amounts of lidocaine will be absorbed by the body compared to the 4% lidocaine patch sold by Defendant.

38. These patches rely on next-generation adhesive mechanisms that allow them to remain affixed to the wearer's body for at least twelve hours under normal conditions.[2]

39. Second, the FDA cautioned manufacturers of OTC analgesic products against making "maximum strength" claims because higher strength and greater potency versions of such items were available with a prescription.

40. Third, the FDA knew other more concentrated and potent similar products could appear in proximity to those represented as "maximum strength" on store shelves.

41. The result would be that consumers would be misled when other companies labeled their products as "regular strength," even though both had the same amount of medication and/or active ingredients.

42. Fourth, given that the Product is explicitly compared to Aspercreme on its front label, "maximum strength" is misleading because the Quality Choice product contains roughly forty percent less lidocaine, even though they have similar or identical dimensions.

43. Fifth, numerous studies and reports revealed that users of adhesive lidocaine patches

[2] In studies, this technology maintained a mean adhesion >90% across all time points (0, 3, 6, 9, and 12 h).

using the same technology used by the Product regularly peel off a user's skin within three to four hours, and sometimes minutes, after being applied.

44. Since, according to the FDA, the actual strength of a lidocaine patch is measured by the "mass of drug relative to the mass of the adhesive per patch" delivered to the target area, these adhesion deficiencies cause the delivery and absorption of lidocaine to be greatly reduced.

45. This inability to adhere for anywhere close to eight hours means the Product cannot deliver the "maximum strength" amount of lidocaine.

IV. DESENSITIZING CLAIMS

46. The Product's promise to "Desensitize[] Aggravated Nerves and Relieve[] Pain" above the radiating, red concentric circles of varying thickness, is misleading because it implies its use will completely block and numb nerves and pain receptors, eliminate responses to painful stimuli and treat neuropathic and musculoskeletal pain.

47. The FDA determined that statements about desensitizing nerves were misleading in the context of transdermal patch delivery systems.

48. This is because consumers, including Plaintiff, associate such statements with medical treatments requiring a prescription and FDA approval.

49. However, the Product is available without a prescription and has not been approved by the FDA.

50. The front label promise to "Desensitize[] Aggravated Nerves and Relieve[] Pain" is inconsistent and contradictory with the Product's limited approval to "Temporarily relieve[] minor pain," indicated in the Drug Facts on the back label.

Jurisdiction and Venue

51. Jurisdiction is based on the Class Action Fairness Act of 2005 ("CAFA"). 28 U.S.C. § 1332(d)(2).

52. The aggregate amount in controversy exceeds $5 million, including any statutory and punitive damages, exclusive of interest and costs.

53. Plaintiff is a citizen of Maryland.

54. Defendant is a citizen of Delaware and Michigan.

55. The members of the class Plaintiff seeks to represent are more than 100, because the Product has been sold with the representations described here for several years, in thousands of stores and online, from national and/or regional pharmacy chains, independent pharmacies, big box stores, warehouse club stores and/or online, in the States covered by Plaintiff's proposed classes.

56. Venue is in this District, with assignment to the Northern Division, because Plaintiff resides in Washington County and a substantial part of the events or omissions giving rise to these claims occurred in Washington County, including Plaintiff's purchases, transactions, and/or use of the Product, exposure to and reliance on the statements in question and awareness and/or experiences of and with the issues described here.

Parties

57. Plaintiff Matthew Ashley is a citizen of Hagerstown, Maryland, Washington County.

58. Defendant Chain Drug Marketing Association, Inc. is a Delaware corporation with a principal place of business in Novi, Michigan, Oakland County.

59. CDMA wholesales and distributes over 1,000 OTC products under its Quality Choice brand through pharmacy chains, independent pharmacies, regional drug wholesalers, specialty

distributors, big box stores, warehouse club stores and/or buying groups.

60. Products under the Quality Choice brand have an industry-wide reputation for quality and value.

61. In releasing products under the Quality Choice brand, Defendant's foremost criteria was ensuring their high-quality, equal to or better than the national brands.

62. That Quality Choice branded products met this high bar was likely proven by focus groups and surveys, rating them above their name brand equivalents.

63. As a result of the false and misleading representations, the Product is sold at a premium price, approximately no less than no less than $9.50 for one package containing five patches, excluding tax and sales, higher than similar products represented in a non-misleading way, and higher than it would be sold for absent the misleading representations and omissions.

64. Plaintiff read and relied on the statements, "Maximum Strength" "Lidocaine Pain Relief Patch," "4% Lidocaine Topical Anesthetic," "Compare [it] to Aspercreme Lidocaine Patch active ingredient*," "Desensitizes Aggravated Nerves and Relieves Pain," "Stay-put Flexible Patch," "Single Use Application" and "Lasts up to 12 Hours," above a human figure with a patch applied to the lower back and red, concentric circles of varying thickness, radiating from the center, which he understood as indicative of the Product's pain relief abilities and effects, such that it could relieve pain beyond the area to which it was applied.

65. Plaintiff purchased the Product at stores including drug stores and/or big box stores in and around the County where he resides between July 2020 and June 2023, and/or among other times.

66. Plaintiff expected the Product to be equal to or greater in quality than the national Aspercreme brand, which he was aware of through its ubiquitous advertising.

67. Plaintiff believed "Maximum Strength" meant that no other lidocaine patches were available, either with or without a prescription, that provided more than 4% lidocaine in patch form.

68. Plaintiff believed that the "4% Lidocaine" meant he would receive this amount of lidocaine, that it would be absorbed by his body such that it could desensitize his aggravated nerves to relieve pain to his body.

69. Plaintiff believed the Product would adhere to his body for close to or not less than 12 hours because it said "Lasts up to 12 hours" in a "Stay-put flexible patch."

70. Plaintiff expected the Product would provide this "Numbing relief" for twelve hours or a small amount of time less than this, because he read "UP TO 12 HOURS" and "Stay-put flexible patch."

71. Plaintiff relied on the words, terms coloring, descriptions, layout, placement, packaging and/or images on the Product, on the labeling, statements, omissions, claims, statements, and instructions, made by Defendant or at its directions, in digital, print and/or social media, which accompanied the Product and separately, through in-store, digital, audio, and print marketing.

72. The Product did not desensitize Plaintiff's nerves, deliver 4% lidocaine, nor stay put for anywhere close to 12 hours, which rendered it unable to provide even temporary pain relief.

73. Plaintiff bought the Product at or exceeding the above-referenced price.

74. Plaintiff paid more for the Product than he would have had he known the representations and omissions were false and misleading, or would not have purchased it.

75. The value of the Product that Plaintiff purchased was materially less than its value as represented by Defendant.

76. Plaintiff chose between Defendant's Product and similarly represented products which did not misrepresent their attributes, features, and/or components.

77. Plaintiff intends to, seeks to, and will purchase the Product again when he can do so with the assurance its representations are consistent with its abilities, attributes, and/or composition.

78. Plaintiff is unable to rely on the labeling and representations not only of this Product, but other similar lidocaine and analgesic patches represented similarly, because he is unsure whether those representations are truthful.

79. If Defendant's labeling were to be truthful, Plaintiff could rely on the labeling of other lidocaine and analgesic patches represented similarly.

Class Allegations

80. Plaintiff seeks certification under Fed. R. Civ. P. 23 of the following classes:

> **Maryland Class:** All persons in the State of Maryland who purchased the Product during the statutes of limitations for each cause of action alleged; and
>
> **Consumer Fraud Multi-State Class**: All persons in the States of Idaho, Alaska, Kansas, Iowa, Mississippi, Mississippi, South Dakota, West Virginia, Arizona and Utah who purchased the Product during the statutes of limitations for each cause of action alleged.

81. Common questions of issues, law, and fact predominate and include whether Defendant's representations were and are misleading and if Plaintiff and class members are entitled to damages.

82. Plaintiff's claims and basis for relief are typical to other members because all were subjected to the same unfair, misleading, and deceptive representations, omissions, and actions.

83. Plaintiff is an adequate representative because his interests do not conflict with other

members.

84. No individual inquiry is necessary since the focus is only on Defendant's practices and the class is definable and ascertainable.

85. Individual actions would risk inconsistent results, be repetitive and are impractical to justify, as the claims are modest relative to the scope of the harm.

86. Plaintiff's counsel is competent and experienced in complex class action litigation and intends to protect class members' interests adequately and fairly.

87. Plaintiff seeks class-wide injunctive relief because the practices continue.

Maryland Consumer Protection Act ("MCPA"),
Commercial Law Art., Md. Code, § 13-101, *et seq.*
(Maryland Class)

88. Plaintiff incorporates by reference all preceding paragraphs.

89. Plaintiff believed the Product (1) provided the maximum amount of lidocaine in patch form, either with or without a prescription, (2) would adhere to his body for twelve hours or very close to this length of time, (3) was similar in quality and ability in terms of pain relief and adhesion, to the Aspercreme lidocaine patch and (4) would desensitize his nerves and relieve pain beyond the area of his body to which it was applied.

90. Defendant's false, misleading and deceptive representations and omissions are material in that they are likely to influence consumer purchasing decisions.

91. Plaintiff would not have purchased the Product or paid as much if the true facts had been known, suffering damages.

Violation of State Consumer Fraud Acts
(Consumer Fraud Multi-State Class)

92. The Consumer Fraud Acts of the States in the Consumer Fraud Multi-State Class are similar to the consumer protection statute invoked by Plaintiff and prohibit the use of unfair or

deceptive business practices in the conduct of commerce.

93. The members of the Consumer Fraud Multi-State Class reserve their rights to assert their consumer protection claims under the Consumer Fraud Acts of the States they represent and/or the consumer protection statute invoked by Plaintiff.

94. Defendant intended that members of the Consumer Fraud Multi-State Class would rely upon its deceptive conduct, which they did, suffering damages.

Breaches of Express Warranty,
Implied Warranty of Merchantability/Fitness for a Particular Purpose
and Magnuson Moss Warranty Act, 15 U.S.C. §§ 2301, *et seq.*

95. The Product was manufactured, identified, marketed and sold by Defendant and expressly and impliedly warranted to Plaintiff that it (1) provided the maximum amount of lidocaine in patch form, either with or without a prescription, (2) would adhere to his body for twelve hours or very close to this length of time, (3) was similar in quality and ability in terms of pain relief and adhesion, to the Aspercreme lidocaine patch and (4) would desensitize his nerves and relieve pain beyond the area of his body to which it was applied.

96. Defendant directly marketed the Product to Plaintiff through its advertisements and marketing, through various forms of media, on the packaging, in print circulars, direct mail, product descriptions distributed to resellers, and targeted digital advertising.

97. Defendant knew the product attributes that potential customers like Plaintiff were seeking and developed its marketing and labeling to directly meet those needs and desires.

98. Defendant's representations about the Product were conveyed in writing and promised it would be defect-free, and Plaintiff understood this meant it (1) provided the maximum amount of lidocaine in patch form, either with or without a prescription, (2) would adhere to his body for twelve hours or very close to this length of time, (3) was similar in quality and ability in

terms of pain relief and adhesion, to the Aspercreme lidocaine patch and (4) would desensitize his nerves and relieve pain beyond the area of his body to which it was applied.

99. Defendant's representations affirmed and promised that the Product (1) provided the maximum amount of lidocaine in patch form, either with or without a prescription, (2) would adhere to his body for twelve hours or very close to this length of time, (3) was similar in quality and ability in terms of pain relief and adhesion, to the Aspercreme lidocaine patch and (4) would desensitize his nerves and relieve pain beyond the area of his body to which it was applied.

100. Defendant described the Product so Plaintiff believed it (1) provided the maximum amount of lidocaine in patch form, either with or without a prescription, (2) would adhere to his body for twelve hours or very close to this length of time, (3) was similar in quality and ability in terms of pain relief and adhesion, to the Aspercreme lidocaine patch and (4) would desensitize his nerves and relieve pain beyond the area of his body to which it was applied, which became part of the basis of the bargain that it would conform to its affirmations and promises.

101. Defendant had a duty to disclose and/or provide non-deceptive descriptions and marketing of the Product.

102. This duty is based on Defendant's outsized role in the market for this type of Product, a trusted company known for its high-quality Quality Choice brand.

103. Plaintiff recently became aware of Defendant's breach of the Product's warranties.

104. Plaintiff provided or provides notice to Defendant, its agents, representatives, retailers, and their employees that it breached the Product's warranties.

105. Defendant received notice and should have been aware of these issues due to complaints by third-parties, including regulators, competitors, and consumers, to its main offices, and by consumers through online forums, review sites and/or its website.

106. The Product did not conform to its affirmations of fact and promises due to Defendant's actions.

107. The Product was not merchantable because it was not fit to pass in the trade as advertised, not fit for the ordinary purpose for which it was intended and did not conform to the promises or affirmations of fact made on the packaging, container or label, because it was marketed as if it (1) provided the maximum amount of lidocaine in patch form, either with or without a prescription, (2) would adhere to his body for twelve hours or very close to this length of time, (3) was similar in quality and ability in terms of pain relief and adhesion, to the Aspercreme lidocaine patch and (4) would desensitize his nerves and relieve pain beyond the area of his body to which it was applied.

108. The Product was not merchantable because Defendant had reason to know the particular purpose for which it was bought by Plaintiff, because he expected it (1) provided the maximum amount of lidocaine in patch form, either with or without a prescription, (2) would adhere to his body for twelve hours or very close to this length of time, (3) was similar in quality and ability in terms of pain relief and adhesion, to the Aspercreme lidocaine patch and (4) would desensitize his nerves and relieve pain beyond the area of his body to which it was applied.

Fraud

109. Defendant misrepresented and/or omitted the attributes and qualities of the Product, that it (1) provided the maximum amount of lidocaine in patch form, either with or without a prescription, (2) would adhere to his body for twelve hours or very close to this length of time, (3) was similar in quality and ability in terms of pain relief and adhesion, to the Aspercreme lidocaine patch and (4) would desensitize his nerves and relieve pain beyond the area of his body to which it was applied.

110. Defendant is a leading seller or private label OTC products, with experience and knowledge to have learned that the Product was not represented in a truthful and non-misleading manner, in accordance with required law and regulations, yet did not do so.

111. The records Defendant is required to maintain, and/or the information inconspicuously disclosed to consumers, provided it with actual and constructive knowledge of the falsity and deception, through statements and omissions.

112. Defendant's fraudulent intent is evinced by its knowledge that the Product was not consistent with its representations.

Unjust Enrichment

113. Defendant obtained benefits and monies because the Product was not as represented and expected, to the detriment and impoverishment of Plaintiff and class members, who seek restitution and disgorgement of inequitably obtained profits.

Jury Demand and Prayer for Relief

Plaintiff demands a jury trial on all issues.

WHEREFORE, Plaintiff prays for judgment:

1. Declaring this a proper class action, certifying Plaintiff as representative and the undersigned as counsel for the class;
2. Entering preliminary and permanent injunctive relief by directing Defendant to correct the challenged practices to comply with the law;
3. Awarding monetary, statutory and/or punitive damages and interest;
4. Awarding costs and expenses, including reasonable fees for Plaintiff's attorneys and experts; and
5. Other and further relief as the Court deems just and proper.

Dated: June 1, 2023

Respectfully submitted,

/s/Spencer Sheehan

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